

Chron  
orig. sent to  
Dr. Shorman

DRAFT: 12/26/73

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Mr. [REDACTED]  
Vice-President

[REDACTED]  
[REDACTED]  
[REDACTED] Illinois [REDACTED]

Dear Mr. [REDACTED]

This is in reply to your recent letter concerning your firm's intention to market a portable [REDACTED] air cleaner for use by consumers. You state that this product may exude ozone or other oxidants into the environment as a result of faulty design or malfunction, and inquire whether the Consumer Product Safety Commission may issue standards relating to generation of oxidants by portable consumer air cleaners.

The Commission has not addressed itself to the question of whether [REDACTED] air cleaners present an unreasonable risk of injury under certain circumstances. However, the matter has received attention from the Food and Drug Administration (FDA). In the near future, FDA will publish regulations on the control of devices which emit ozone, whether by design or inadvertence. The substance of these regulations can be found in a proposed policy statement published in the Federal Register on June 27, 1972, a copy of which is enclosed for your information. The statement indicates that ozone is a toxic gas; thus, it would appear that toxicity is a characteristic to be avoided whether the ozone is emitted from a medical device and therefore regulated under the Federal Food, Drug and Cosmetic Act, or a consumer product and subject to the provisions of the Consumer Product Safety Act (CPSA).

You may wish to contact the FDA to ascertain the circumstances under which air cleaners are subject to regulation as medical devices. For guidance in determining whether the product you intend to manufacture may be a consumer product, there is also enclosed a copy of the Consumer Product Safety Act. If it should develop that your air cleaner is not a medical device it would

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be subject to all the provisions of the CPSA, including the obligation under Section 15 to notify the Commission of any defects which could create a substantial risk of injury to the public.

Sincerely,

L. James Sharman  
Director  
Office of Standards Coordination  
and Appraisal

Enclosures

BPitkin:mab:12/26/73

cc: L. J. Sharman  
M. Brown  
B. Pitkin